



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

8/11

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/818,683	03/28/2001	Ping Feng	PZ020P1C1	3074
22195	7590	03/09/2004	EXAMINER	
HUMAN GENOME SCIENCES INC INTELLECTUAL PROPERTY DEPT. 14200 SHADY GROVE ROAD ROCKVILLE, MD 20850				CLOW, LORIA
ART UNIT		PAPER NUMBER		
		1631		

DATE MAILED: 03/09/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/818,683	FENG ET AL.	
	Examiner	Art Unit	
	Lori A. Clow, Ph.D.	1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on 09 December 2003.

2a) This action is **FINAL**. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) Claim(s) 25-58 is/are pending in the application.
4a) Of the above claim(s) 27,30-34,39,42-48,51 and 54-58 is/are withdrawn from consideration.

5) Claim(s) _____ is/are allowed.

6) Claim(s) 25,26,28,29,35-38,40,41,49,50,52, and 53 is/are rejected.

7) Claim(s) _____ is/are objected to.

8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) All b) Some * c) None of:
1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. _____.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) Notice of References Cited (PTO-892) 4) Interview Summary (PTO-413)
2) Notice of Draftsperson's Patent Drawing Review (PTO-948) Paper No(s)/Mail Date. ____ .
3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____ .
5) Notice of Informal Patent Application (PTO-152)
6) Other: ____ .

DETAILED ACTION

Applicant's arguments filed 9 December 2003 have been fully considered. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Claims 25-58 are currently pending.

Election/Restrictions

Applicant states that the Examiner has treated Applicant's sequence election as an election without traverse and state that in the previous response the provisional election to the claimed polypeptide sequence was made with traverse. However, this is not the case and the Examiner would like to point Applicant to the response dated 16 July 2003, in which Applicant provisionally elected, *with traverse*, the invention of Group III, represented by original claims 11, 12, 16 and 23 (now cancelled) and new claims 25-54, *inter alia*, polypeptides, for prosecution on the merits (see page 9 of response). The Examiner stated in the Office Action dated 9 September 2003 that in the original Restriction Requirement a single sequence should have been chosen. Applicant has elected SEQ ID NO: 466, which does not include Gene 83 or ATCC Deposit Number HNTB157 (see page 2 of Office Action). Applicant did not traverse the sequence election requirement, only the Group election. Applicant's argument are therefore not found persuasive for the reasons set forth in the Restriction/Election Requirement. In the requirement, specific distinctions between the multiple inventions and multiple sequences were set forth and as such the requirement is still deemed proper and is made FINAL.

Claims 27, 30-34, 39, 42-48, 51, and 54-59 remain withdrawn. Applicant argues that the polypeptides encoded by HNTB157 cDNA contained in ATCC Deposit Number 209423 do not constitute a separate and distinct invention. Applicant asserts that a search of SEQ ID NO: 93 would yield the polypeptide encoded by SEQ ID NO: 466 and the polypeptide encoded by the HNTB157 cDNA contained in ATCC Deposit Number 209493. This argument is not persuasive. Applicant has failed to provide evidence or support that this is in fact true. The specification, according to Table 1, indicates that SEQ ID NO: 93 corresponds to the amino acid sequence SEQ ID NO: 221. Nowhere does the table indicate that SEQ ID NO: 93 encodes an amino acid of SEQ ID NO: 466.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 25-29, 35-41, and 49-53 remain rejected under 35 U.S.C. 101 because the claimed invention lacks patentable utility, for the reasons set forth in the Previous Office Action.

Applicant argues that the Examiner has acknowledged that Applicants have asserted utilities in the specification and that these have been dismissed as being insubstantial or non-specific. Further Applicant's argue that an asserted utility is specific to the subject matter claimed and that the utilities for SEQ ID NO: 466 are specific in that not every protein is expressed primarily in fetal lung, stromal cells, and lymphoma cells.

This argument is not persuasive, as there is nothing in the specification that states that SEQ ID NO: 466 has a specific utility. Just because SEQ ID NO: 466 may be detected in fetal lung, stromal cells, and lymphoma cells, there is nothing in the specification that identifies SEQ ID NO: 466 as being **specific** to only these tissues. The specification is devoid of any information with regard to expression levels such that the detection of SEQ ID NO: 466 would be indicative of anything. SEQ ID NO: 466 is only mentioned in the specification at page 165 as being part of Gene 83. Absent that description there is no evidence that SEQ ID NO: 466 has a specific utility.

Applicant further argues that based on the disclosure it would be reasonable to assert that the claimed invention is useful as a diagnostic marker for haematopoietic and respiratory disorders. However, the specification, again, does not disclose these uses as they pertain to SEQ ID NO: 466. Furthermore, how could a sequence that is expressed in fetal lung tissue be indicative of a respiratory disorder? The specification does not disclose that this is expressed in diseased lung tissue. Furthermore, what specific diseases could this be used for? All haematopoietic and respiratory diseases or disorders? There is no disclosure of specific assays that have been run, for example, to compare diseased to non-diseased tissue to screen for upregulation or down regulation of SEQ ID NO: 466, such that it may be utilized for a marker for a specific cancer. It is maintained that the examples in the specification are generic in nature and not specific to the elected sequence.

Claims 25-29, 35-41, and 49-53 remain rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific, substantial, or

credible utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 25-29 and 49-53 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. *This is a new matter rejection.*

Claim 25 and dependent claims are drawn to an isolated protein comprising amino acid residues 2 to 341 of SEQ ID NO: 466. However, there is no support in the specification for this particular fragment as it relates to SEQ ID NO: 466. Pages 283-284 only recite generic fragment sizes, but do not teach 2-341. The only mention in the specification of SEQ ID NO: 466, besides the sequence listing at page 206, is at page 165 as part of a bigger sequence which makes up Gene 83.

Claim 49 and dependent claims are drawn to an isolated protein consisting of at least 30 contiguous amino acid residues of amino acid residues 1 to 341 of SEQ ID NO: 466. However, there is no support in the specification for a fragment of “at least 30 contiguous amino acids”

relating specifically to **any** SEQ ID NO. Applicant has pointed to pages 283-285 for support of the fragments, however, the support recited is not specific to SEQ ID NO: 466.

No claims are allowed.

Inquiries

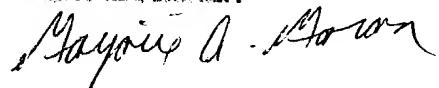
Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 CFR § 1.6(d)). The CM1 Fax Center number is either (703) 308-4242, or (703) 308-4028.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lori A. Clow, Ph.D., whose telephone number is (571) 272-0715. The examiner can normally be reached on Monday-Friday from 10 am to 6:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael P. Woodward, Ph.D., can be reached on (571) 272-0722.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Legal Instrument Examiner, Tina Plunkett, whose telephone number is (703) 305-3524, or to the Technical Center receptionist whose telephone number is (571) 272-0549.

MARJORIE MORAN
PATENT EXAMINER



March 2, 2004

Lori A. Clow, Ph.D.

Art Unit 1631

